# PREEMPTING THE PUBLIC INTEREST

How TTIP Will Limit US States' Public Health and Environmental Protections



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### About CIEL

Founded in 1989, the Center for International Environmental Law (CIEL) uses the power of law to protect the environment, promote human rights, and ensure a just and sustainable society. CIEL is dedicated to advocacy in the global public interest through legal counsel, policy research, analysis, education, training, and capacity building.



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### Acknowledgements

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AmCham EU — US Chamber of Commerce in Europe

CIEL — Center for International Environmental Law

CLA — CropLife America

CPSC — US Consumer Products Safety Commission

EPA — US Environmental Protection Agency
ECPA — European Crop Protection Association

EU — European Union

FDA — US Food and Drug Administration

FIFRA — Federal Insecticide, Fungicide and Rodenticide Act

FFDCA — Federal Food, Drug, and Cosmetic Act

FQPA — Food, Quality Protection Act

ISDS — Investor-State Dispute Settlement

MRL — Maximum Residue Levels

NAFTA — North America Free Trade Agreement

OIRA — Office of Information and Regulatory Affairs

RCB — Regulatory Cooperation Body

REACH — Registration, Evaluation, Authorisation and Restriction of Chemicals

SPS — Sanitary and phytosanitary measures

TBT — Technical barriers to trade

TPP — Trans-Pacific Partnership Agreement

TSCA — Toxic Substance Control Act

TTIP — Trans-Atlantic Trade and Investment Partnership Agreement

UBA — German Environment Agency

US — United States

USCIB — United States Council for International Business

USTR — US Trade Representative

# **Executive Summary**

◀he proposed chapter on Regulatory Cooperation in the Trans-Atlantic Trade and Investment Partnership (TTIP) Agreement, the largest bilateral trade agreement in history, threatens the authority and independence of US state governors, legislators, and executive agencies, and would fundamentally alter how environmental policy is developed, enacted, and implemented in the United States.

TTIP's regulatory cooperation provisions are intended to reduce the cost of doing business by minimizing regulation, promoting convergence of regulatory standards, and defaulting to international standards developed with significant involvement of the regulated industries. These goals can only be achieved by preventing US states from adopting health and environmental regulations that go beyond US federal standards.

This regulatory agenda is being pushed by the largest chemical and manufacturing corporations on both sides of the Atlantic. Largely frustrated in their past attempts to have the US Congress preempt US state standards that go beyond federal minimums, these corporations have now turned to international trade agreements, including TTIP, to undermine state regulations by other means. In the absence of comprehensive federal standards, state legislatures have become the primary vehicle for much of the United States' chemical regulation. Interference with state regulatory authority will have major implications on public health, safety, and welfare in the US.

During the past three decades, while the federal Toxic Substance Control Act (TSCA) has proven egregiously ineffective, US states have adopted more than 250 laws and regulations protecting humans and the environment from exposure to toxic chemicals, and they have taken the lead in enforcing stricter pesticide standards. California is one of several states to design chemical policies to protect consumers from potentially hazardous products. Likewise, as the US federal government has failed to respond to fracking concerns, states have filled the regulatory void; in 2015 alone, 226 bills addressing hydraulic fracturing were proposed in 33 states.

US states have also extended regulatory authority over pesticides, implementing bans, overseeing registrations and labels, and imposing restrictive use standards. The US Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is actually designed to promote co-regulation between the federal and state governments, yet states are the predominant regulator under this Act. This often leads to stricter standards and more stringent protocols at the state level. New York and California have banned several pesticide products deemed acceptable by the EPA, and Kansas and Iowa are among many states that require more rigorous registration, application, and use standards than those federally required.

TTIP's Regulatory Cooperation chapter threatens to undermine these protections to public health, welfare, and safety by explicitly targeting US state laws and regulations throughout. The US has not publicly responded to these detrimental impacts, nor addressed several of TTIP's ambiguities that require clarification. For example, it remains unclear whether Investor-State Dispute Settlement (ISDS) arbitration will serve as an avenue for recourse for non-compliance claims.

Although there have been limited efforts to promote "good regulatory practices" and international cooperation in prior US trade and investment agreements, the US regulatory framework has never before faced the unexpected and novel challenges that TTIP presents. The proposals for regulatory cooperation and coherence in TTIP delve deeply into the internal legislative and regulatory decisions and choices of US states, as well as the federal government. They do so in ways not an-

ticipated by the US Constitution, and in the process pose significant risks not only to our capacity to regulate to protect public health and environment, but also to our democratic institutions.

The Regulatory Cooperation chapter not only disrupts the US legislative pathways by weakening state regulatory authority, but it will also threaten the independence of state agencies and regulatory bodies. The chapter would institutionalize new avenues for private interests to seek to influence decision-making before legislation is introduced and to suppress laws and regulations before they are enacted. Industries will no longer be limited by the democratic process of a legislature with public hearings and opportunities to provide testimony, but can instead influence an unelected, unaccountable, and currently ill-defined international trade oversight body.

As proposed by the EU, an "early warning" system will inject additional, behind-thescenes industry influence that will promote newly required alternatives and trade impact analyses and drive a race to the bottom based on preferred "least trade restrictive" policies. In addition to "paralysis by analysis," these harmonization requirements could also lead to a freeze on future protections as US states seek to avoid legal challenges by transnational corporations seeking millions of dollars in compensation in special arbitration proceedings.

The ultimate outcome of these provisions will dramatically impair health and environmental protections across the US, and erode the authority of US states to regulate in the public interest. Not only is this result contrary to the historic role of states as the frontline protectors of public health and safety, it will halt the innovation and responsiveness of state policy-makers to emerging technologies and health threats, leaving millions of Americans at risk.

# **Key Messages and Recommendations**

- The TTIP Regulatory Cooperation chapter proposed by the EU will comprehensively apply to both US state and EU Member State legislative and regulatory measures, and new procedural requirements will apply to legislative bodies as well as executive agencies.
- The scope of any US regulatory proposal in TTIP is unknown, because the US refuses to publicly release any text. The United States Trade Representative (USTR) has yet to publicly address the details of the EU text or similar industry-drafted regulatory cooperation proposals that seek to prevent US states and EU Member States from implementing regulatory standards that exceed federal or central government minimum standards.
- US states have wide latitude to regulate to protect public health, safety, and welfare under the US Constitution and federal environmental laws, most of which institutionalize a strong role for states as co-regulator. With federal regulation of chemical hazards lax, slow, or simply broken, many states have assumed primary responsibility for developing regulations to protect the public and the environment, including restrictions on the use of certain toxic chemicals in consumer products, labeling for increased consumer awareness, tighter controls on fracking waste, and greater scrutiny in determining whether pesticides are safe.
- Viewed as a whole, the EU's Regulatory Cooperation chapter has the potential to negate important existing and future
- protections from toxic chemicals in the United States. The sweeping scope of covered laws and regulations, the failure to preserve any right to regulate outside of the federal government, and the avowed goal of achieving "regulatory compatibility" between the EU and US central governments all threaten the continuing viability of US state laws and regulations that are more protective than federal standards.
- Cooperation provisions will extend well beyond encouraging good governance and voluntary transatlantic cooperation. The chapter will impose multiple procedural mandates from an early warning system to regulatory exchanges to the trade and cost-benefit impact assessments that will lead to a regulatory chill caused by delay, increased costs for government, fear of legal challenges, and heightened industry influence and conflicts of interest.
- To an unprecedented degree, US federal agency bureaucrats will become involved in state legislative and executive branch procedures and policies. In addition, the concerns of foreign governments will be inserted into US state domestic policy decisions.
- It is imperative that state government officials and civil society act promptly to expose the details of TTIP proposals and to speak out in opposition in light of the fast pace of TTIP negotiations, the limits placed on Congressional oversight following approval of "fast track" review, the failure of the USTR to operate in a transparent manner, and the absence of any public push-back by the US government against EU and industry Regulatory Cooperation proposals.



# I. Introduction

he proposed Trans-Atlantic Trade Investment Partnership (TTIP) Agreement, currently under negotiation between the United State and European Union, would be the largest bilateral trade agreement in history. Unlike earlier trade agreements focused on reducing tariffs to open markets, TTIP is primarily intended to reduce or eliminate regulatory differences between the US and EU.

Eighty percent of TTIP's hypothetical economic benefits are estimated to come from reducing regulatory differences between the US and EU.1 These regulatory differences, characterized by industry as regulatory barriers to trade, often are the result of progress toward stronger protections for public health, workers, consumers and the environment.

Both the US and EU are pushing to conclude TTIP negotiations before President Obama leaves office in January of 2017. Recently, US Congress passed Trade Promotion Authority (or "Fast-Track") legislation, which prevents Congress from proposing changes to the final agreement to address concerns. The House and Senate must approve trade deals "as-is," in an expedited process with an up or down vote.

The regulatory objectives of the EU and US for TTIP, including applying broad-reaching regulatory cooperation, convergence, and coherence obligations on the US states, are largely driven by industry. The US Chamber of Commerce in Europe (AmCham EU), argues in a position paper that:

> "Regulatory convergence is needed inside both trading partners. Both in the US and

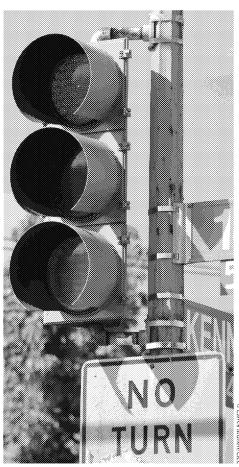
in Europe, state or national and in some cases local regulations act as barriers to trade and prevent companies from benefitting from economies of scale."2

Similarly, the American Chemistry Council (ACC), which represents most of the largest and most powerful chemical companies, developed detailed textual proposals for convenient adoption and use by the US and EU, many of which implicate US states' authority.3

Efforts by ACC and other chemical trade associations to preempt state regulatory authorities have been one of the most controversial aspects of US chemical reform.4 If TTIP is approved by the US Congress and European Parliament it will establish rules governing state and local laws and regulations, as well as federal law. These state regulations are extensive; the US Constitution provides wide latitude to state governments to regulate to protect the public interest. Federal environmental laws - on toxic chemicals, waste disposal, pesticides, air, and water pollutionmake clear that federal standards are a "floor," not a "ceiling," and that state governments may set more protective standards.

This report analyzes the potential impacts of "regulatory cooperation" proposals in TTIP on the ability of US states to regulate in the public interest. Although regulatory cooperation will also impact EU Member States, detailed analysis of EU impacts is outside the scope of this report. The report focuses primarily on EU textual proposals, because no US proposals are public. Section II describes the scope and legal basis of US

state-level laws and regulations addressing toxic chemicals. Sections III and IV describe what is publicly known about EU and US proposals on regulatory cooperation and coherence, respectively. Section V describes how these regulatory cooperation provisions may affect US state-level legislative and regulatory procedures and outcomes, and Section VI provides an analysis of the specific impact on toxic chemical regulation at the state level in the US.



# II. US State Regulation of Chemicals and Pesticides

tates have wide latitude to regulate to protect the public health, safety, and welfare under the US Constitution, and federal environmental laws generally protect states' authority to regulate and even share regulatory authority, particularly when the federal government fails to act. With federal regulation of chemical hazards lax, slow, or simply broken, many states have assumed primary responsibility for developing regulations to protect the public from exposure to toxic substances. These protective health and environmental regulations include:

- restrictions on the use of certain toxic chemicals in consumer products;
- labeling requirements providing increased consumer awareness;
- tighter regulations to control fracking waste; greater scrutiny in determining whether pesticides are safe; and
- disclosure requirements for hazardous substances in fracking fluids, pesticide formulations, consumer products, and other potential sources of human exposure to toxic chemicals.

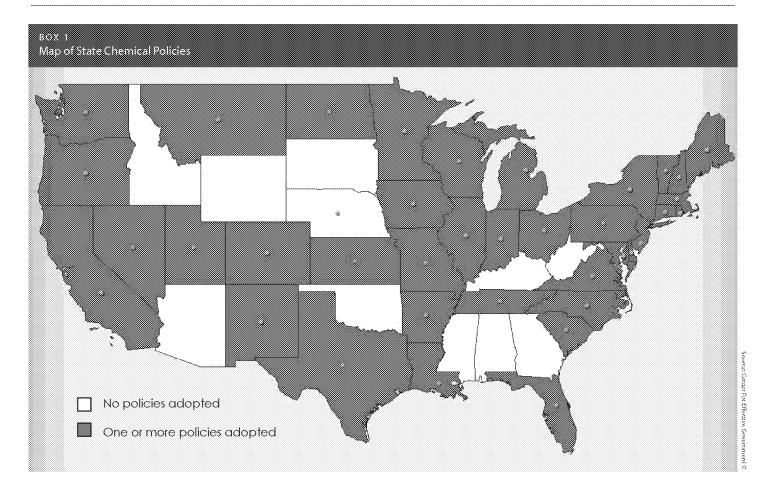
State policy on chemicals and consumer products. Over the past 30 years, 38 states have adopted more than 250 laws and regulations to protect their residents and environment from exposure to those chemicals.<sup>5</sup> Under the primary federal chemical statute, the Toxic Substance Control Act (TSCA), "States have broad authority to directly regulate and restrict toxic chemicals in the manufacturing, processing, distribution, use, and disposal stages."6 As a recent American Bar Association report observed, "[i]n fact, states are generally free to impose restrictions on any chemical substance if EPA [Environmental Protection Agency] has not specifically addressed that substance under the statute."7 States can also regulate even where EPA has acted if the state regulation is identical to the federal regulation, if the state regulation is adopted under the authority of another federal law, or if the state simply bans the use of a chemical substance or mixture within its borders.8

TSCA is the poster child for ineffective federal laws. Indeed, the President's Cancer Panel Report called it "the most egregious example of ineffective regulation of chemical contaminants." The US federal government "is still stuck with obsolete and ineffective legislation from the 1970s that has yielded – with the exception of the ban on PCBs – virtually no meaningful national regulation of thousands of toxic substances in nearly 40 years." For example, of the 84,000 chemicals on the TSCA inventory, only 200 have undergone health and safety testing before entering the market.

Two bills to overhaul TSCA currently pending in Congress contain provisions expanding the scope of state preemption. However, preemption is a contentious issue that is still being debated. In both Senate and House TSCA bills, preemption would be triggered if and when the federal EPA acts to regulate particular chemicals that overlap with state standards. Historically, action on toxic chemicals has been very slow at the national level, and the pace is unlikely to accelerate significantly even if these measures become law, meaning that states will likely retain a critical role in enacting new chemical protections. Both bills also provide that states are always free to act under the authority of other federal laws.12

Consumer product safety is likewise lightly regulated under the weak and ineffective federal Consumer Products Safety Act and subsequent statutes specific to toys and imported products. The US Consumer Products Safety Commission (CPSC) has issued very few regulations. In fact, the CPSC "is required to rely on industry-developed voluntary safety standards to address product hazards any time a voluntary standard is an adequate means of addressing the hazard and enjoys significant compliance by the affected industry" and the federal agency "rarely undertakes the laborious process of crafting mandatory safety standards" even where industry standards are in-





adequate. <sup>13</sup> US states are free to regulate where the CPSC has failed to act. <sup>14</sup> As a practical matter, with so few mandatory federal consumer product standards, state regulation has proceeded largely unhindered. <sup>15</sup>

With federal regulation so lax, many states have in effect taken over primary responsibility for developing regulations to protect the public from exposure to toxic substances. These state-level initiatives gained momentum following the enactment by citizen initiative of California's Safe Drinking Water and Toxic Enforcement Act, also known as Prop 65, in 1986. This law requires manufacturers to prominently display warnings on products that contain any of the now over 800 chemicals listed by the state as causing cancer or reproductive harm.<sup>16</sup>

Many products are marketed throughout the US in packaging with these warning labels, giving the California law national reach. Prop 65 continues to have national and international significance. On September 4, 2015, California's environmental agency proposed labeling the widely used herbicide ingredient glyphosate (marketed by Monsanto for household and agricultural use as a weed killer

under the product name "Roundup") as a "probable carcinogenic" pursuant to Prop 65. The announcement follows a March 2015 classification of glyphosate by the International Agency for Research on Cancer (IARC) – the World Health Organization's cancer arm – as known to cause cancer.<sup>17</sup>

"[TSCA is] obsolete and ineffective legislation from the 1970s that has yielded - with the exception of PCBs - virtually no meaningful national regulation of thousands of toxic substances in nearly 40 years."

Since passage of Prop 65, an increasing number of states across the US have enacted chemical policies, including measures to protect children from toys with toxic components, to ban toxic ingredients from food packaging, to label and impose producer responsibility for disposal or other end-of-life handling on manufacturers of products containing mercury and other heavy metals, and to require disclosures of ingredients and display health warnings. Because of these efforts, in many states and localities across the country, dangerous chemicals like mercury,

lead, bisphenol-A (BPA), cadmium, formaldehyde, hexavalent chromium, nonylphenol and nonylphenol ethoxylates (potential endocrine disruptors), perchloroethylene, and polybrominated diphenyl ether flame retardants are banned in consumer products.<sup>18</sup>

Of particular significance, five states – California, Maine, Minnesota, Oregon, Vermont, and Washington – have established a rigorous process to define hazardous chemicals of greatest concern to vulnerable populations, with authority to require reporting and disclosure and to regulate, including banning products, based on the level of risk.<sup>19</sup> This trend continues: in 2015, thirteen bills related to chemical prioritization were pending in eight state legislatures.<sup>20</sup>

In an ironic twist, these US state chemical policies are an example of "upward harmonization" with the EU. The measures rely on the supporting scientific studies and regulatory model of the EU's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) program, which unlike the US federal chemical law, generally requires the submission of safety data before high hazard chemicals can be registered and marketed.<sup>21</sup>

### BOX-2 States Move to Regulate Microbeads in Absence of Federal Action

In the first few months of 2015, Republican and Democratic legislators in 25 states introduced legislation to ban synthetic microbeads in personal care products, including cosmetics and drugs. These materials bypasses water treatment systems, contaminates waterways including the Great Lakes, and ultimately is ingested by fish, which may in turn be ingested by people. These states were following the lead of Illinois and New Jersey, where similar legislation had already passed. By June



2015, bills had become law in Colorado, Indiana, Maryland, and Maine.<sup>22</sup>

State pesticide policy. To a large degree, US states co-regulate pesticides with the EPA and other federal agencies. New York passed the first pesticide law in the nation in 1898, and California followed in 1901, well before the federal government began regulating.<sup>23</sup> States have retained significant regulatory authority even with the passage of federal pesticide laws. This authority is critical to maintain because of significant lapses in oversight by the federal government. The EPA often allows a pesticide to enter the market pending approval, meaning before any evaluation has been done. This aspect of the process has been overused and abused, enabling potentially extremely dangerous pesticides to remain on the market.24 Consequently, the US lags far behind the European Union, which has banned 82 pesticide ingredients it considers dangerous, but which continue to be legally sold in the US.25

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), states may develop and enforce regulations more stringent than federal rules, including:

- denying pesticide product registration and the right to market and use a pesticide in the territory of the state;
- regulating products exempted from registration by the EPA;
- requiring manufacturers to provide additional studies and data not required by federal law;
- affecting the content of manufacturer's product labels; and
- setting more restrictive application and use standards.

Additional data requirements. Manufacturers frequently must submit additional information, data, and studies to address concerns raised by state regulators during registration reviews. For example, California requires extensive additional data *that is not required by EPA* on potential human health and environmental effects associated with use of a product prior to registration, including:

- product composition and chemistry;
- acute and chronic toxicity;
- how pesticide behaves in environment;
- effectiveness against targeted pests;
- hazards to nontarget organisms;
- effects on fish and wildlife; and
- worker exposure.<sup>26</sup>

California mandates registrants of pesticides registered before 1984 to bring health effects data on their products up to current scientific standards, and does not permit the registration of new active ingredients without a full complement of health effects studies, addressing chronic as well as acute toxicity, and a range of reproductive effects.<sup>27</sup> Florida requests additional data or studies to complete modeling scenarios for state-specific conditions for approximately 65% of the New Active Ingredient registration requests submitted to the state. On average, 30% of these products are registered with "conditions."<sup>28</sup>

Product bans. New York State has refused to register numerous products registered by the EPA, preventing those products from being legally distributed, offered for sale, or used in the state. State regulators "perform an extensive review of pesticide products which contain new active ingredients and/or are considered to represent major changes in labeling." <sup>29</sup> In Florida, if the registrant cannot provide the requested data, the registrant withdraws its pesticide registration application request -a de facto ban. <sup>30</sup>

California has suspended the registration and sale of dozens of federally permitted pesticides after reviewing health data or because manufacturers have failed to submit required data. The state's 1984 Birth Defect Prevention Act requires submitting additional health data relating to birth defects for previously registered pesticide ingredients. If continued use of a pesticide is determined to present a significant health hazard that cannot be adequately mitigated, the state must cancel the registration of products containing that active ingredient.31 Government reports illustrate the significance of California's heightened scrutiny of pesticide health hazards. Of the 200 pesticides identified in the 1984 law for priority data review, by 2001, manufacturers withdrew 47 products from the market and the state suspended eight for failure to submit required data. A second round of data submissions was initiated in 1992 for 703 registered active ingredients not on the priority list. Of these, only 198 had complete data on file by the end of 2010. The vast majority of the remaining 500plus active ingredients were either withdrawn from the market or suspended and effectively banned by the state.32

Registration of "exempt" pesticides. If EPA exempts a pesticide product from FIFRA, states may nonetheless impose their own registration requirements and prohibit the sale, distribution, or use of that product in their state. Maryland has exercised this authority to regulate products EPA designates "Minimal Risk Pesticides," which otherwise would avoid any registration and review before use in the state.<sup>33</sup> Kansas requires any pesticide containing a drug to be registered as a pesticide, whereas EPA does not consider these products pesticides and leaves regulation to the Food and Drug Administration (FDA).<sup>34</sup>

Label revisions. Although FIFRA has language preempting states from setting their own requirements for pesticide labels – the mechanism used by FIFRA to regulate application and use for registered products – in effect state regulation causes manufacturers to change product labels in order to be allowed

to sell or use those products in the state. Florida and New York are examples of this; as large markets, these states effectively set their own label requirements.35 New York is also one of the only entities at either the state or federal level to review final product container labeling. The state performs a side-by-side review of the container labeling and the EPAstamped "Accepted" labeling. As New York's top pesticide registration official observes, "We often find label discrepancies. If the discrepancies cannot be resolved, the application for registration is denied in New York State."36

More restrictive application and use standards. States are allowed to set more restrictive application and use standards, and do so through a variety of state-law mechanisms without modifying a federally-approved label. State governments license pest control companies that operate within their states, certify individual pest control applicators, establish rules governing buffer areas and drift, regulate container disposal and storage, investigate complaints, and enforce state and federal pesticide laws. They also may apply more strin-

gent rules to pesticides when acting under the authority of other environmental statutes such as the Clean Water Act.37

Several states in EPA's Region 7 have pursued this strategy, according to the EPA and state officials. For example, Iowa restricts Atrazine application rates to less than that allowed by the federal label in certain counties in the state in order to protect water quality, and Kansas is more stringent than the federal label in how structural pesticides may be applied.38 Nebraska is in the final stages of promulgating a regulation to create a State Management Plan for Pesticides in Water Resources that would authorize restrictions on specific active ingredients where pesticide contamination of water resources in excess of established health or ecological criteria is found.39

Protecting consumers from pesticide residue on food. In the US, primary authority to establish allowable levels of pesticide residue on food rests with the federal government pursuant to the Food Quality Protection Act (FQPA). However, according to the EPA,

states still can regulate: "states are preempted only with regard to tolerances/exemptions for pesticide chemicals that have been reassessed against the new safety standard or initially assessed against that standard and found to meet it."40 Further, even though the federal Food, Drug and Cosmetic Act (FFDCA) regulates food labeling generally, according to the EPA, "Nothing in FFDCA preempts states/political subdivisions from requiring food containing a pesticide chemical residue to bear or be subject of a warning or other statement related to the presence of the pesticide chemical residue."41

These state regulations and enforcement actions clearly impact not only domestic but internationally sourced food products. California, which first began analyzing produce for pesticide residues in 1926,42 has an extensive pesticide residue monitoring program with significant consequences when EPA tolerances are exceeded, including imposing quarantines or destroying contaminated produce.43

### BOX States Enact Pollinator Protections in Absence of Federal Action

US states have jumped into a void created by a lack of regulation at the federal level and started regulating bee-killing pesticides that threaten the food supply and ecological balance. Among the states that have already taken action:

Minnesota - Prohibits labeling or advertising a plant, plant material, or nursery stock as beneficial to pollinators if the plant was treated with an insecticide that was absorbed by the plant and, as a result, the plant is lethal to pollinators (HB 2798 - 2014). The state also authorizes enforcement action for violations of law that result in harm to pollinators, including applying a pesticide in a manner inconsistent with the product's label and authorizes compensation in certain situations for bees killed by acute pesticide poisoning. (HB 3172 - 2014)

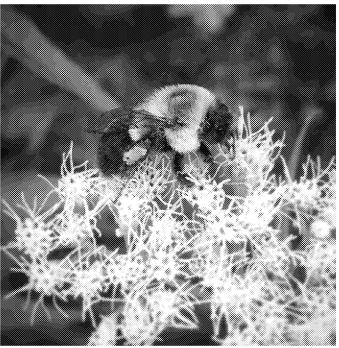
California - Requires state regulators to complete the reevaluation of neonicotinoids' effects on pollinator health by July 1, 2018, and to adopt control measures necessary to protect pollinators within two years of issuing the determination. (AB 1789 - 2014)

Indiana - Prohibits individuals from producing, transporting, storing, handling, or disposing of any pesticide or pesticide container in a manner that may cause injury to beneficial insects, including pollinators. (SB 314 - 2008)

Oregon - Requires Oregon State University to develop educational materials regarding best practices for avoiding adverse effects of pesticides on populations of bees and other pollinating insects. The materials must be included as part of

the education required for the pesticide applicator licensing examination. (HB 4139 - 2014)

Vermont - Requires the state Secretary of Agriculture, Food & Markets to evaluate the effect of neonicotinoid pesticides on human health and the health of bees and other pollinators. (HB 869 - 2014)44





State Fracking Policy. In addition to imposing tighter standards on chemical and pesticide use, state regulators are venturing significantly beyond the limited federal regulation of hydraulic fracturing (fracking) under the authority of federal laws protecting air and water quality and regulating waste disposal.

- Connecticut law establishes a three-year moratorium on fracking waste handling and disposal until the state adopts regulations to control fracking waste as a hazardous waste, and imposes licensing and information disclosure requirements.
- California requires an independent

scientific study and a permit before performing any treatments on hydraulic fracturing wells, and online reporting and disclosure of well treatment fluids and volume of water used in hydraulic fracturing.

- Maryland law establishes a moratorium on fracking or exploratory wells related to fracking until October 1, 2017, after state regulations are expected to be adopted.
- New York is regulating high volume hydraulic fracturing under existing oil and gas mining laws. A final health and environmental impact statement with a

decision to ban fracking is possible later this year. New York's action was precipitated by a plethora of bans and moratoria adopted by local governments in New York.<sup>45</sup>

In 2015, there were 226 bills in 33 state legislatures concerning hydraulic fracturing. 46 Given the number of bans and moratoria enacted by municipalities and counties across the country, coupled with lax regulation at the federal level, additional state fracking measures are both sorely needed and highly likely in the coming months and years. 47

# III. Details of the EU's TTIP Regulatory Cooperation Proposal

The EU's revised Textual Proposal for a Chapter on Regulatory Cooperation, which was made public May 4, 2015,48 would establish an ongoing, unelected regulatory oversight entity composed of trade functionaries and regulators from both the EU and US. This entity would, in multiple ways, monitor the actions of elected officials and administrative agencies at both the central and non-central levels of government, with the objectives of facilitating trade and investment and reducing "unnecessarily burdensome, duplicative or divergent regulatory requirement affecting trade or investment."49

In sum, the EU proposes to

- create an overarching regulatory oversight body to minimize regulatory divergence between the EU and US;
- increase US federal government oversight of the states' regulatory decision-making;
- potentially apply new procedural and substantive requirements to almost all state-level legislation and regulation;
- potentially erase protective regulatory differences between the states; and
- potentially subject states through international arbitration challenges to increased legal liability for exercising their Constitutional authority to protect people and the environment.

US states and EU member nations ("non-central governments") would be covered by most of the provisions of the EU's proposed Chapter on Regulatory Cooperation. The current draft only partially spells out the scope of US states' obligations and how non-central government compliance would be achieved, especially with respect to legislative bodies. This may reflect not only the political sensitivity of this proposal but also fundamental differences between the EU and US organizing structures, particularly the principle of federalism pursuant to which US states retain significant independent authority to regulate to protect health, safety,

and welfare. There are many bracketed placeholders applicable to non-central government throughout the text.50 Nonetheless, taken as a whole, the expressed intent is to apply the provisions comprehensively to US state government legislation and regulation.

The fifty US states<sup>51</sup> (and the national governments of the EU Member States) will be directly affected by the harmonization and regulatory review initiatives of the Regulatory Cooperation Body, the centerpiece of the EU's proposal. These non-central governments will be subjected to many procedural requirements, such as the broadly-applied "early warning" system to alert EU trade functionaries (and presumably, industry stakeholders) to proposed legislation and regulations, and, for selected regulatory acts yet to be identified, information exchanges between governments. It is unclear whether non-central governments will be required to submit their regulatory acts for cost benefit and trade impact assessments; a footnote leaves open the possibility of this burdensome and time-consuming requirement.52 These obligations will be coordinated

at the federal and international levels with the goal of reducing impacts on trade or investment.

Non-central governments will also be indirectly affected even where the text purports to apply only to the central governments. Specifically, provisions aimed at achieving "regulatory compatibility" between US and EU regulatory regimes will necessarily result in limiting US states' regulation. If the EU and US effectively harmonize federal regulations, US states will no longer have the latitude to adopt and enforce standards that exceed the protections offered at the federal level. Moreover, nothing in the text expresses intent to maintain any regulation below the federal, or central, level of government, in parallel with this harmonization drive.

Federal government oversight of us state compliance with regulatory cooperation. The proposed chapter on Regulatory Cooperation would obligate the US federal government to play a major role in overseeing, monitoring, and enforcing the regulatory



cooperation provisions as they apply to the "laws and regulations adopted by the central authorities of a US state," and to "regulators and competent authorities at the non-central level."53 The term "central government authorities" of US states is not defined but presumably includes at least governors, executive branch agencies, and legislatures. The US federal government would be required to establish or designate a "Focal Point" agency to oversee compliance with the provisions of the chapter relating to "envisaged and existing regulatory acts" at both the central and non-central (US state government) levels. The draft includes a bracketed placeholder promising "further details on the Focal Points at the non-central level."54

The US federal government Focal Point is directed to provide information about state government "planned regulatory acts or planned changes to existing regulatory acts" upon the request of EU officials. US state-level "planned regulatory acts" are not defined. 55 When EU officials request a regulatory exchange concerning a specific planned or existing regulatory act at the state level, the federal government "will take steps to accommodate such a regulatory exchange" and "shall solicit the responsible regulators and competent authorities at non-central level to engage in regulatory exchanges." 57

Although the EU fact sheet explaining the Regulatory Cooperation chapter asserts that the participation of state government officials in these exchanges is voluntary,<sup>58</sup> the actual text is less clear. The onus is on federal officials to convince state regulators to participate. Whether the exchange proceeds without a state's involvement if it declines to participate, and whether action can be taken against either the federal or state governments if they fail to carry out their respective obligations, is not spelled out.<sup>59</sup> The non-central regulatory exchanges will be "led by the regulators and competent authorities responsible for the regulatory acts;" US federal officials and their EU counterparts will "facilitate" the exchanges.<sup>60</sup>

In addition to these regulatory exchanges contemplated for "planned acts" of state governments, the EU proposes "more detailed provisions on regulatory cooperation" concerning *other* state-level regulatory acts that will be addressed in other "specific or sectoral" chapters of TTIP *yet to be identified.*<sup>61</sup>

What might these additional provisions include? Publicly released EU proposals for chapters on food and animal and plant health (Sanitary and Phytosanitary measures or SPS) and Technical Barriers to Trade (TBT) are singled out for mention in the prefatory notes to the Regulatory Cooperation chapter. These chapters, which broadly apply to state laws and regulations and have implications for state regulation of pesticides and chemicals, are discussed in more detail below.<sup>62</sup>

Additional provisions targeted for regulatory exchanges presumably will be specified in

future TTIP textual proposals; the only regulation specifically referenced in this draft is mutual recognition of professional qualifications.63 In the context of state environmental policies, this could apply to certification and training requirements for pesticide applicators, which in the US is solely a state government responsibility. The scope of these regulatory exchanges aimed at harmonization is unlikely to be limited to aligning professional qualifications, however. The EU's fact sheet on regulatory cooperation mentions nine sectors for possible harmonization initiatives: automobiles, chemicals, cosmetics, pharmaceuticals, information, communications and technology (ICT), engineering, financial services, medical devices, and textiles.64

Provisions almed at achieving "regulatory compatibility" between US and EU regulatory regimes will necessarily result in limiting US states' regulation. If the EU and US effectively harmonize federal regulations, US states will no longer have the latitude to adopt and enforce standards that exceed the protections offered at the federal level.

Other provisions further extend the reach of this chapter over US state governments. Article 14.1 establishing the ongoing bilateral "Regulatory Cooperation Body" (RCB) explicitly applies to "both regulatory acts at central *and non-central level.*" A footnote applicable to Section III, Articles 8-16 notes that "except where indicated otherwise Articles in this section apply to *both* regulatory acts at central and non-central level (notably Articles 12-16).66

Unfortunately, read in the context of the agreement itself, the "except where indicated otherwise" limitation affords almost no meaningful protection for state level regulators. For example, Article 8, "Bilateral Cooperation Mechanism," has a bracketed placeholder promising further details on its applicability to non-central governments. Article 9, "Information and Regulatory Exchanges on regulatory acts at central level" seemingly is limited to central governments, but a footnote encourages "regular direct contacts between regulators and competent regulatory authorities at central or non-central level."67 Article 11 "Information and Regulatory Exchanges on regulatory acts at non-central level" by its terms applies to US states, and parallels the



central-level requirements of Article 9. This leaves only Article 10 "Promoting regulatory compatibility at the central level" not directly applicable to US state governments. Unfortunately, as we discuss below, this article has *indirect* applicability to US state regulatory activities, and leaving non-central regulation out of the scope of Article 10 could result in overriding, not protecting, US state regulations.

SCOPE OF LEGISLATION AND REGULATIONS COVERED. The Regulatory Cooperation chapter would apply to a "regulatory act at the non-central level," defined as "laws and regulations adopted by the central authorities of a US state." The intent seems to broadly cover US state laws and regulations under both Section II "Good Regulatory Practice" and Section III "Regulatory Cooperation." Nonetheless, the inclusion of footnotes urging "further reflection" and "further discussion" concerning applicability to non-central governments renders the current text incomplete and unclear.

Section II includes provisions requiring early notice of planned legislation and regulations, stakeholder consultations, and trade and investment impact assessments. It applies to regulatory acts addressing any policy area "not excluded from the scope of TTIP" that determine requirements or related procedures for either the supply or use of a service, such as "authorization, licensing or qualification." This section also applies to the "characteristics, related production methods...presentation, or ...use" of goods marketed in the EU or US.<sup>69</sup>

SERVICES COVERED. While the scope of services covered by TTIP's Regulatory Cooperation chapter (and other chapters) is subject to negotiation between the EU and US, the EU has stated its interest in TTIP significantly contributing to services markets, and EU negotiators made an expansive initial services offer in July 2015.70 The EU's services and investment offer includes, with some reservations, environmental services, energy services including distribution such as pipelines, harbor dredging, and telecommunications among other services.<sup>71</sup> "Environmental services" includes a broad array of government and commercial activities under World Trade Organization definitions and EU bilateral treaties, including the recently negotiated agreement with Canada. Examples of state regulations that could be covered by the services definition



include licensing of landfills, hazardous waste incinerators, and pesticide applicators; and permits for oil, gas and electricity generation, storage and distribution, and water and sewage treatment.<sup>72</sup>

Examples of state regulations that could be covered under regulatory cooperation include product specifications such as restrictions on certain chemicals in cosmetics, children's toys and food packaging, environmental regulations applicable to manufacturing facilities such as paper mills and chemical factories, garbage incinerators, nuclear power plants and liquefied natural gas, consumer product labeling, and pesticide registration and restrictions on when and where they are applied.

GOODS COVERED. The range of goods covered is also likely to be expansive. Examples of state regulations that could be covered by the goods definition include product specifications such as restrictions on certain chemicals in cosmetics, children's toys and food packaging, environmental regulations applicable to manufacturing facilities such as paper mills and chemical factories, garbage incinerators, nuclear power plants and liquefied natural gas, consumer product labeling, and pesticide registration and restrictions on when and where they are applied.<sup>73</sup>

Section III, which includes provisions relating

to Regulatory Cooperation including the bilateral regulatory cooperation body, information exchanges, and promoting "regulatory compatibility," applies to central *or non-central level regulatory acts* which meet any of the criteria outlined above and "that have or are likely to have a significant impact on trade or investment" between the EU and US. In addition, *any* regulatory act covered by yet-to-be-identified "specific or sectoral provisions concerning goods and services" in *any other chapter* of the TTIP comes within the scope of this chapter.<sup>74</sup>

This is very broad language indeed. First, a regulation need not impact trade at all to trigger the chapter's requirements – an impact on investment is sufficient. It seems likely that most US state consumer and environmental regulations that exceed federal standards could be found to "impact" investment, since they generally impose costs not already required by federal law. The requirement that the impact be deemed "significant" is unlikely to narrow the scope of this provision substantially; as we point out below [see discussion of OIRA at p20], similar limiting language in the US regulatory review context has had no practical effect.

Second, the language cross-referencing other chapters of TTIP would likely trigger coverage of the vast majority of any remaining state consumer and environmental regulations – apparently even if those regulations have *no impact on either investment or trade*. For example, we know the EU is seeking sectoral chapters on cosmetics, energy and raw mate-

rials, and chemicals, 75 and as discussed above, the EU's own regulatory cooperation "fact sheet" lists nine possible chapters where harmonization would be appropriate. 76 US states have enacted legislation in all of these policy areas, and will continue to so in the future. Any such state-level legislation could thus be automatically swept within the ambit of this section.

In fact, the Regulatory Cooperation chapter nowhere specifically exempts any regulatory acts of US states. This contrasts with how EU Member State regulatory acts are treated. The definition of a covered "regulatory act" of an EU Member State specifically excludes laws and regulations "that transpose into domestic law European Union acts." A parallel exclusion is not, however, provided for US state laws and regulations that implement federal law, or where US states have been delegated authority under federal statute.77 Yet, as detailed in Section II of this paper, US federal environmental laws are generally premised on the enactment and implementation of state laws and regulations that carry out federal directives. In addition, these statutes and the US

Constitution grant states authority to regulate in areas where federal regulation is limited and where states have traditionally exercised police power authority to protect the public health, safety and welfare.

The sweeping scope of the Regulatory Cooperation chapter as applied to US state legislation and regulations is even more troubling because the chapter lacks any "savings clause" that would protect the right of non-central governments to regulate. While the Preamble includes "right to regulate" language and the "General Objectives and Principles" asserts that the provisions of this chapter "do not restrict the right of each Party to maintain, adopt and apply timely measures to achieve legitimate public policy objectives... at the level of protection that it considers appropriate," this language applies only to the *Parties*—the EU and the US national governments.<sup>78</sup>

ENFORCING THE REGULATORY COOPERATION OBLIGATIONS. The current draft does not address how state legislators and regulators will be made to comply with the many obligations imposed by this chapter. In particular, it is

unclear whether lack of compliance could be subject to dispute settlement in a trade case brought by the EU, or by an investor using Investor-State Dispute Settlement (ISDS) arbitration. The prefatory "general notes" observe that regulatory cooperation procedures "may not lend themselves to the application of dispute settlement rules." The notes suggest "regular monitoring and reporting" including involving the trade ministers of the EU and US as a possible enforcement mechanism.<sup>79</sup>

This equivocal language does not clearly rule out ISDS or government-to-government dispute settlement for failure to comply with this chapter. This conclusion is buttressed by the different treatment accorded in another policy area, financial services, that the text asserts "should not be subject to dispute settlement." In addition, as we discuss in Section VI of this report, even if the Regulatory Cooperation chapter does not itself include ISDS, the assessments and regulatory exchanges required by this chapter could well open the door to attacks on US state regulations in corporate arbitration proceedings under TTIP's investment chapter.

# IV. Details of Potential USTR Regulatory Coherence Proposal

he US government has refused to publicly release any of its TTIP proposals. This lack of transparency is exacerbated by the vague nature of public statements on regulatory cooperation released by USTR, which employ ambiguous, ill-defined catch phrases such as transparency, evidence-based analysis, and whole-of-government coordination. USTR has stated it endorses "a range of regulatory cooperation tools as well as other steps aimed at reducing or eliminating unnecessary regulatory differences."81

A leaked Regulatory Coherence draft chapter from the Trans-Pacific Partnership (TPP), a trade agreement that is simultaneously under negotiation by the US government and closer to completion, may offer insight into what the US government is seeking in TTIP.<sup>82</sup> Features of this chapter include:

- a process or mechanism with significant reach at the central level of government to coordinate and review new regulatory measures;
- 2. regulatory impact analyses;
- identifying and assessing alternatives including voluntary measures and a decision not to regulate;
- 4. cost-benefit analysis;
- decisions based on the best reasonably obtainable scientific, technical, economic, and other information;" and
- 6. annual advance notice of planned regulatory measures.

The leaked Transpacific Partnership (TPP) text provides important and consistent detail to USTR's broad public statements, particularly the focus on cost-benefit analysis, assessing alternatives to regulation including voluntary measures, and the "whole-of-government" approach to regulatory management.<sup>83</sup>

Applicability to US state governments. Clearly, many of the features outlined in this Transpacific Partnership document overlap with the EU's proposed TTIP Regulatory Cooperation chapter. One difference may be how these provisions would apply to non-central governments. The TPP text has only general language seeking "channels of communication" between federal and state governments, and does not appear to apply directly to legislation and legislators at either the federal or state levels of government. In that respect it differs from the EU's TTIP Regulatory Cooperation chapter, which applies throughout to US state legislatures and to Congress, as well as both federal and state executive agencies responsible for adopting regulations.

The lack of specific language directed at state regulators and legislators in the US regulatory cooperation proposals may ultimately not change the overall impact of these provisions. The US is clearly seeking to bind state governments in *other* TTIP chapters that are intended to harmonize regulations between the

EU and US. USTR has endorsed the recommendations of the Joint EU-US High Level Working Group on Jobs and Growth84 which has a strong focus on reducing business costs through regulatory cooperation measures, calling for an "ambitious 'SPS-plus' chapter" and measures "based on science and on international standards or scientific risk assessments, applied only to the extent necessary" and an "ambitious 'TBT-plus' chapter" with a goal of "convergence in regulatory approaches and requirements" ... "to reduce redundant and burdensome testing and certification requirements."85 These objectives have also been strongly endorsed by, among other business interests, the US Chamber of Commerce, a powerful USTR "stakeholder" representing many industries that serve on USTR advisory committees. The Chamber has its own 19page regulatory cooperation and coherence proposal that is consistent with the leaked TPP text but far more detailed and coercive.86



# V. The Impact of EU and USTR Proposals on US States

he TTIP regulatory cooperation and coherence proposals threaten the authority and independence of US state governors, legislators and executive agencies, and could fundamentally alter how public policy is developed, enacted and implemented in the United States. From what we know - the US text is secret - there are similar elements in both US and EU proposals. In fact there is a real danger that in the behind-closed-doors negotiation sessions, the two proposals will be merged to produce a "worst of all worlds" scenario or a skeletal agreement with critical details missing or to be determined at a later date. The German Environment Agency (UBA) recently warned that the "improper design of regulatory cooperation in TTIP carries potentially significant environmental risks."87

Regulatory cooperation and coherence have nothing to do with trade. Rather, as Professor

Jane Kelsey has written, "Coherence' refers to the internal regulatory decisions and choices of the state. This is achieved by imposing disciplines on its bureaucratic structure, decision-making processes and criteria." The proposals for regulatory cooperation and coherence in TTIP delve deeply into the internal legislative and regulatory decisions and choices of US states as well as the federal government. They do so in ways not anticipated by the US Constitution, and in the process pose significant risks not only to our capacity to regulate to protect public health and environment, but also to our democratic institutions.

A key feature of TTIP is the creation of a "living agreement." As the cautionary report of the UBA explains: "The free trade agreement TTIP has the declared objective to unify standards — as much as possible — even in the environmental field. This aim cannot and will not be fully achieved by the time the contract

is concluded. Instead, the harmonisation of standards is meant to continue in the framework of regulatory cooperation."89

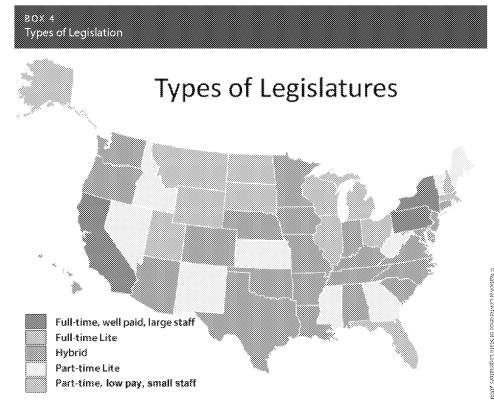
The proposals for regulatory cooperation and coherence in TTIP delve deeply into the internal legislative and regulatory decisions and choices of US states as well as the federal government. They do so in ways not anticipated by the US Constitution, and in the process pose significant risks not only to our capacity to regulate to protect public health and environment, but also to our democratic institutions.

If this is so, then it matters greatly who is at the table making these important decisions, whether decision-making is transparent and inclusive, and whether the underlying principles of a government and the choices made by democratically elected officials guide the results. Unfortunately, the TTIP regulatory proposals fail on all counts, and will lead inexorably to deregulation, delayed and weakened environmental standards, less transparency, more conflicts of interest, and more industry influence.

### The Regulatory Cooperation chapter will:

INSTITUTIONALIZE THE MONITORING AND REVIEW OF PROPOSED ACTIONS OF STATE OFFICIALS AND AGENCIES BY FEDERAL GOVERNMENTS

The EU's Regulatory Cooperation chapter would interject the concerns of foreign governments into US states' domestic policies and procedures. Approximately 7,383 state legislators, 90 50 governors and countless state agencies will be caught up in a red tape-creating review process that will give foreign governments and the trade interests they rep-



### вох Maines Path to Legislation



### IDEA DEVELOPED

a legislator decides to sponsor a bill, sometimes at the suggestion of a constituent, interest group, public official or the Governor. The legislator may ask other legislators in either chamber to join as co-sponsors.



### BILL DRAFTED

At the legislator's direction, the Revisor's Office, Office of Policy and Legal Analysis, and Office of Fiscal and Program Review staff provides research and drafting assistance and prepare the bill in proper technical form.



### BILL INTRODUCED

The legislator gives the bill to the Clerk of the House or Secretary of the Senate. The bill is numbered, a suggested committee recommendation is made and the bill is printed. The bill is placed on the respective body's calendar.



### COMMITTEE REFERENCE

The bill is referred to one of the Joint Standing or Joint Select committees in the originating branch and then sent to the other body for concurrence.



### COMMITTEE ACTION

When scheduled by the chairs, the committee conducts a public hearing where it accepts testimony supporting and opposing the proposed legislation from any interested party. Notices of public hearings are printed in newspapers with statewide distribution.



### **GENERAL ORDER**

When the bill is reported to the floor it receives it's first reading and any committee amendments are adopted at this time. The committee reports the bill to the originating body as is, with amendment, with a divided report or with a unanimous recommendation of Ought Not to Pass.



### SECOND READING

The next legislative day the bill is given its second reading and floor amendments may be offered. When one chamber has passed the bill to be engrossed, it is sent to the other body for its consideration. The House has

a consent calendar for unanimous Ought to Pass or Ought to Pass as amended bills which takes the place of First and Second readings.



### SECOND CHAMBER

The bill goes through a similar process. If the second chamber amends the bill, it is returned to the first chamber for a vote on the changes. It may then be sent to a conference committee to work out a compromise agreeable to both chambers. A bill receives final legislative

approval when it passes both chambers in identical form.



### **GOVERNOR**

After final passage (enactment) the bill is sent to the Governor. The Governor has ten days in which to sign or veto the bill. If the Governor does not sign the bill and the Legislature is still in session, the bill after ten days becomes law as if the Governor signed it. If the Legislature has adjourned for the year the bill does not become law. This is called

a "pocket veto." If the Legislature comes back into special session, the Governor on the 4th day must deliver a veto message to the chamber of origin or the bill becomes law.



### LAW

A bill becomes law 90 days after the end of the legislative session in which it was passed. A bill can become law immediately if the Legislature, by a 2/3 vote of each chamber, declares that an emergency exists. An emergency law takes effect on the date the Governor signs it unless otherwise specified in its text. If a bill is vetoed, it will become law if the Legislature overrides the veto by a 2/3 vote of those members present and voting of both chambers.

and voting of both chambers.

resent advance notice of proposed legislation and regulations, and an opportunity to review draft policies even before they are formally proposed. This pre-review system would step on legislative procedures and subvert the public hearing process by granting EU trade bureaucrats preferential access in order to promote their agenda of facilitating trade and investment and reducing "unnecessarily burdensome, duplicative or divergent regulatory requirement affecting trade or investment. TTIP is likely to have a similar effect on Member States of the EU, opening the door to increased US engagement and interference.

IMPOSE ONEROUS BURDENS ON OVER-STRETCHED STATE REOURCES

This oversight and monitoring will itself be "unnecessarily burdensome," imposing costs of time and money on US state institutions that are chronically understaffed, short of funding, and less equipped to defend proposed measures against complex transatlantic negotiations and arguments premised on obscure international trade rules. These costs are not trivial; they will in fact shift resources from frontline staff and programs protecting the environment to compiling lists of legislation and interacting with US

federal and EU officials in "regulatory exchanges." State legislatures are particularly ill-equipped to participate meaningfully in any of these activities. A small minority of legislatures are fully staffed and considered full-time operations; most are part-time "citizen legislatures" with virtually no staff available to participate in collating documents listing regulatory acts or supporting legislators' participation in regulatory exchanges.91

**ERODE THE INDEPENDENCE OF STATE AGENCIES** AND REGULATORY BOARDS

Although many state agencies already compile publicly available regulatory agendas under their state versions of the Administrative Procedures Act, they do not necessarily funnel their legislative proposals through a governor's office or other centralized review. It is not uncommon for state regulatory boards and high-level agency officials to be independently elected and thus not fully within the purview of a governor's office, including for example, state attorneys general, agriculture and mining commissioners, and public utility regulators. The EU's advance review requirement and, if applied to US states, USTR's "whole of government" management of regulation would

necessitate central coordination and erode the independence of these state agencies.

INCREASE FEDERAL INTERVENTION IN STATE LEGISLATIVE AND REGULATORY INITIATIVES

Both the EU-proposed federal "focal point" and the US-proposed "whole of government" approach to regulatory management would maximize federal interference in state legislative and regulatory activities. The EU's "focal point" proposal would require US authorities to intervene in state government by collecting information on proposed legislation and regulation, soliciting and presumably enforcing state regulatory agency and legislative participation in information exchanges, and facilitating and leading the exchange meetings. This would further add to the onerous burdens described above.

The US focal point would be required to deal with the relevant "central government authorities." Currently, federal agencies interact with state executive agencies, not legislatures, when coordinating on joint initiatives or state implementation of federal laws with state responsibilities. Trade policy is communicated through a "state point of contact," appointed by governors.92 Yet the EU's proposal sweeps state legislatures into its ambit. If this proposal goes through, the US government will need to establish multiple state points of contact, including with legislatures – or risk elevating governors over a separate and equal branch of government. The US government's role is less clear under its own proposal, which is not public. Based on USTR statements, a federal agency such as the Office of Management and Budget, which already monitors and reviews federal regulations, could have a beefed-up role monitoring state activities.

The requirement to provide advance notice of regulatory acts is not a mere procedural step without substantive consequences. Depending on the state, governors may have discretion to introduce legislation when deemed necessary, and without advance notice even to the legislature. State legislatures also determine their own rules of procedure that determine when bill drafts and titles are disclosed. A TTIP advance notice obligation would unilaterally change these organizational rules without the participation of state legislators and governors in the decision to make those changes - after all, neither US state legislators nor governors get to vote on whether to approve TTIP.

CREATE A CHOKEPOINT THAT WILL DELAY AND DEFER US STATES'ENVIRONMENTAL REGULATION

USTR is apparently seeking to incorporate into international trade agreements a domestic regulatory review and management model that has a terrible history of delaying, diluting and disrupting important health and safety rules – the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.<sup>93</sup> Although it is unclear whether the USTR will seek to extend this oversight in TTIP to US state regulations, there is every possibility that negotiations will produce a merged USTR-EU Regulatory Cooperation chapter that incorporates elements of the US approach.

The EU "focal point" proposal has significant similarities to the current US federal regulatory review process. If the existing US review process becomes a model for implementing the US state government oversight functions called for in the EU's regulatory cooperation proposal, then TTIP will create a chokepoint with the potential to delay important health and environmental protections for years.

As the OIRA review process currently op-

erates, federal regulations deemed "significant" - and even more regulations that are not considered "significant" but somehow end up shunted into this process94 - must undergo regulatory and cost-benefit impact assessments before the rules can be adopted in final form. It is worth noting that the EU's regulatory cooperation proposal purports to limit many of its requirements to "significant" non-central regulatory acts. Given the experience with OIRA, such a limitation would have little practical effect. Indeed, under the current US federal regulatory review process, environmental and public health measures are disproportionately selected for review, resulting in proposed rules being withdrawn completely, re-proposed, and delayed as additional studies are completed. The end result has been lives lost and health compromised.

Under the current US federal regulatory review process, environmental and public health measures are disproportionately selected for review, resulting in proposed rules being withdrawn completely, re-proposed, and delayed as additional studies are completed. The end result has been lives lost and health compromised.

Studies of OIRA conclude that the process has worked to:

- enhance the influence of big business and regulated industries in the development (and defeat) of regulations;
- allow money to influence regulatory priorities and outcomes;
- insert conflicts of interest both early and late in regulatory process;
- limit transparency and prevent accountability, by providing an end run around the public record;
- disproportionately target health and environmental regulations for review and revision; and
- increase inefficiency, by encouraging duplicate submissions and meetings, and multiple bites of the apple, by industry opponents of the proposed regulation.<sup>95</sup>

Regulations that have gone into this bottleneck only to be delayed indefinitely or merely excessively include workplace exposure rules, formaldehyde regulations, chemical regulation generally, and arsenic levels in drinking water and pesticides. In the first half of 2013, two dozen OIRA regulatory reviews took longer than a year to complete, and the 140-day average review time during the first half of 2013 included a number of reviews that took nearly two years to complete. 6 US regulators are still struggling to protect workers from lung-damaging silica 40 years after being warned about it. Protective silica regulation has been repeatedly stalled by the federal regulatory review process, including for two and a half years languishing in OIRA – despite the fact that there is a 90-day deadline for review. 97

In fact, the federal regulatory process is one reason that US federal environmental regulation is frequently long-delayed or weak, necessitating state governments to step into the breach. Extending any comparable process to regulatory efforts at the state level would pose a serious new threat to progress in environmental, health, and safety standards across the country.

INCREASE CONFLICTS OF INTEREST AND UNDUE INDUSTRY INFLUENCE ON REGULATORY ACTIONS

The regulatory cooperation provisions would make it more difficult to adopt US state-level chemical policy by increasing industry influence in multiple ways:

- by relying- on international standards that are heavily influenced and often directly written by industry;
- by requiring early warning of proposed laws and regulations that impose costs on industry;
- through the operation of the Regulatory Cooperation Body which will invite industry stakeholders to comment on regulatory cooperation initiatives and to participate in sectoral working groups;
- by creating back-door access to regulators during "regulatory exchanges" outside of the more transparent and accountable notice and comment and public hearing process; and
- by establishing additional meeting and review processes that favor corporate interests with deep pockets and large lobbying staffs over staff and resource-poor civil society and public interests.

The net result of this additional, substantive access will be greater influence over both state-level policies and federal standards that through the harmonization provisions will become the regulatory ceiling.

PRIORITIZE TRADE CONSIDERATIONS OVER PUBLIC HEALTH AND ENVIRONMENT THROUGH IMPACT ASSESSMENT AND LEAST TRADE RESTRICTIVE ALTERNATIVES ANALYSES

Both the US and EU regulatory cooperation proposals would require regulatory or trade impact assessments for many proposed regulations and laws. At this time it is unclear the extent to which these requirements would be imposed on US state governments; the EU indicated in a footnote that it is considering applying the requirements for trade impact assessments on non-central regulatory acts.

The lack of objectivity in costbenefit analysis in general, which has been demonstrated time and again to undervalue health and environmental harms while overestimating industry compliance costs, is well-established by empirical research.

It costs money and takes time to perform cost benefit and regulatory impact statements, resulting in delays to critical health and safety measures, and providing grounds for legal challenges. The lack of objectivity in cost-benefit analysis in general, which has been demonstrated time and again to undervalue health and environmental harms while over-estimating industry compliance costs, is well-established by empirical research. The fact that the regulated industries control access to much of the information needed to assess compliance costs - by claiming "confidential business information" - further skews this supposedly "scientific" and "objective" exercise into anything but.98

TTIP's Regulatory Cooperation chapter would superimpose trade and financial concerns over other critically important public policy objectives, requiring impact assessments for many regulations prior to enactment. In addition to resulting in "paralysis by analysis," this requirement could well open the door to attacks on state and federal regulations in corporate arbitration proceedings. For example, government-produced documents such as trade impact assessments, or any finding by the Regulatory Cooperation Body that a non-central law or regulation is more "trade restrictive" than central level regulations, could be used by investors to support challenges to US state laws pursuant TTIP's proposed investor protection provisions.99

# TTIP is Already Being Invoked to Slow Regulatory Progress

Industry, together with allies in the US Government, has used TTIP's regulatory coherence objectives to stall the prospect of more protective laws in the EU, while simultaneously supporting bills in the US Congress that would further entrench divergent regulatory practices between the US and EU. In the EU, industry and the US government lobbied fiercely to prevent the EU from regulating hormone (endocrine) disrupting chemicals. 104 Both industry and the US government have used TTIP's regulatory cooperation and coherence objectives to prevent the EU from enacting stronger measures for these chemicals of concern. The US Government sent a letter in January of 2015, threatening that the EU taking a different approach than the US would be contrary to the "primary objective" of TTIP.105

Ironically, industry supported bills that are now pending in the US Congress to "reform" the broken US system for regulating industrial chemicals (TSCA) bear no resemblance to stronger, more protective counterparts in the EU. This comes despite repeated calls for closer regulatory cooperation and greater regulatory coherence between the US and EU by industry. This double talk makes it apparent that TTIP would not be used to elevate standards of protection when opportunities present themselves, but rather to weaken, slow, or stop the development and implementation of stronger rules for toxic chemicals on both sides of the Atlantic.



Investor challenges under ISDS provisions in other agreements have disproportionately targeted environmental and public health policies. Recent cases relevant to state-level chemical and environmental regulation include Lone Pine's attack on a fracking moratorium enacted by the Quebec provincial government in Canada and a judgment in support of Bilcon's challenge to the Nova Scotia provincial government's denial of a mining permit. The specter of a possible ISDS case can create a chilling effect for regulators wary of being forced to defend a state-level regulation. 100

Threats of litigation, whether in domestic courts or corporate tribunals, are especially

common when US states innovate and respond to emerging health threats or act in the absence of federal regulation.101 The cost just for defending a challenged policy in an ISDS forum is \$8 million on average. 102 Although US state governments are not currently required to pay the costs of an ISDS case, which is defended by the US federal government, participation even as an amicus or by assisting federal lawyers is expensive. State attornevs general, many of whom who had to use state resources to defend their state's tobacco regulations against ISDS challenges under NAFTA, have raised these concerns about excessive costs with USTR.103

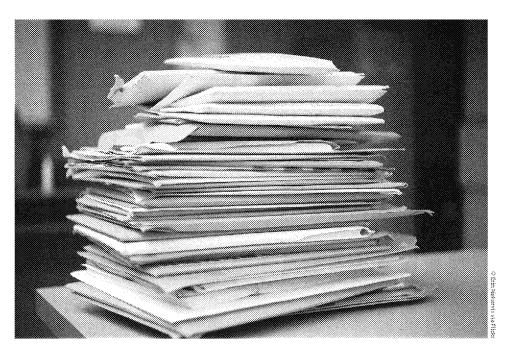
# VI. The Impact on Public Health and Environmental Protections: The Case of Toxic Chemicals and Pesticides

Tiewed as a whole, the regulatory cooperation chapter has the potential to negate important existing and future protections from toxic chemicals in the United States. The failure to preserve any non-central right to regulate in the public interest, the sweeping scope of covered laws and regulations, and the avowed goal of achieving "regulatory compatibility" between the EU and US central governments, all threaten the continuing viability of US state laws and regulations that are more protective than federal standards.

While proponents of regulatory cooperation claim its procedural provisions simply insure good government, in fact the additional requirements will stifle continued effective US state regulation. The many hoops that state regulators will have to jump through – from the early warning system to the regulatory exchanges to the trade and cost-benefit impact assessments – will lead to regulatory chill caused by delay, increased costs for government, fear of legal challenges, and heightened industry influence and conflicts of interest.

The regulatory compatibility and harmonization provisions will be used to attack state chemical and pesticide regulations. Testifying on the benefits of TTIP, the United States Council for International Business (USCIB) stated that TTIP should "Prohibit subsidiary political units from imposing approval requirements or restrictions. Approval by the EU or US federal authorities should be adequate to ensure safety across the entire US or the European Union. Subsidiary political units, such as EU Member States or US States should be prohibited from seeking to impose separate requirements for approval or local restrictions on sale or use." 106

In effect, the USCIB called for TTIP to prevent US states from continuing most of their current regulation of pesticides. The USCIB's views are consistent with those of many busi-



ness interests that support TTIP. Unfortunately, the priorities of the USCIB and the transnational businesses it represents are clearly reflected in the Regulatory Cooperation chapter and other TTIP provisions.

The threat to state laws and regulations is most directly expressed in Article 10 of the chapter, which seeks to achieve regulatory compatibility through harmonization, mutual recognition of equivalence, or simplification of regulations between the EU and the US central governments. This initiative ignores the entirety of US state (and EU member government) chemical and other environmental regulation. There is no place for state regulators and legislators in the process outlined in Article 10, which applies only to central governments. There is no discussion of mutual recognition of non-central standards; achieving "regulatory compatibility" will be based on weak federal or international standards, discussed below. US state regulations that are more protective of human health and the environment will not be aligned with these federal standards, and when trade impact assessments are completed, it is a given that these standards will be considered not "least trade restrictive" in comparison. They could then be targeted for federal preemption by US Congress or challenged under TTIP's investor protections.

State laws detailed in Section II of this report, regulating toxic substances in consumer goods, fracking waste, and pesticides could all be vulnerable under either or both sectoral and horizontal regulatory harmonization provisions. For example, a mutual recognition approach applied to consumer products would undermine state-level standards including bans on formaldehyde-treated furnishings or mercury-containing children's toys. The Consumer Product Safety Commission's over-reliance on voluntary standards and the limited regulation of chemicals under TSCA would become the regulatory ceiling instead of a floor. State standards could also be attacked under TTIP's food safety (SPS) chapter, which the EU's Regulatory Cooperation chapter specifically cross-references and makes applicable to US states.

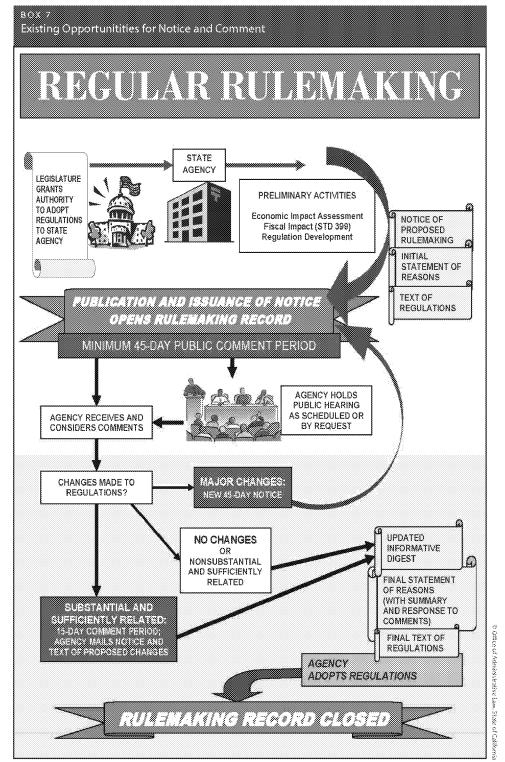
For example, the Institute for Agriculture and Trade Policy suggests that US state and EU Member State restrictions on the use of Bisphenol A (BPA), a known endocrine disrupter and possible carcinogen, would be vulnerable to attack under the regulatory cooperation provisions of TTIP's food safety (SPS) chapter, because neither the US nor the EU central governments have comprehensively banned using BPA in food packaging. "(R)egulatory harmonization could lead to a harmonization of BPA standards so that California and other US state[s] could be obliged to allow European Union imports packed in materials containing BPA."107 Ten US states have BPA restrictions, many of which go beyond the FDA standard,108 which bans BPA in children's sippy cups but not other products or food packaging.109

Article 10 also seeks to harmonize regulatory acts through the "application of existing international instruments" as well as developing new international standards.<sup>110</sup> This provision is consistent with the wishes of CropLife America (CLA) and the European Crop Protection Association (ECPA). CLA and ECPA produced a joint proposal on US-EU regulatory cooperation that sought to "harmonize" pesticide standards by defaulting to the international Codex Alimentarius and replacing the EU's precautionary principle with the much weaker "science-based risk assessment" standard used by the US. CLA and ECPA also suggest a separate pesticides chapter and favor keeping key regulatory data secret.111

As CIEL has documented, the Codex standards for pesticide residues on food are generally significantly less protective than EU food safety standards, while often, but not always, more restrictive than US maximum residue levels (MRLs). They also are applied differently; for example, extrapolating data from one product to another without regard to conditions of use, application, formulation and climate.112 Moreover the content of these standards is heavily influenced by industry interests. Harmonizing EU and US pesticide regulations by either defaulting to the Codex standards or through mutual recognition would threaten US state pesticide standards and enforcement that are more protective than US federal law. Applying the provisions of the EU's proposed SPS chapter, which is incorporated by reference into the Regulatory Cooperation chapter, would have the same result.

The EU's SPS chapter provides that once SPS measure is approved by a competent authority of the importing territory, products to which the measure are applied must be accepted everywhere in the importing territory. This "once approved, accepted everywhere" approach, promoted by the USCIB and its chemical and pesticide industry allies, appears in direct conflict with California's proactive independent monitoring and enforcement of pesticide residue standards. Under California

law, if illegal residues are found (either above the tolerance or with no tolerance for that combination of commodity and pesticide), the state removes the illegal produce from sale, verifies that the produce is either destroyed or returned to its source, acts to quarantine other produce from the same source, and works with federal Immigration and Customs Enforcement to identify and eliminate sources of illegal residues in imported produce. Violators can also be fined.<sup>114</sup>



The procedural provisions of the Regulatory Cooperation Chapter will likely delay US state regulation of chemicals while increasing opportunities for industry influence and reducing the transparency of regulatory decisions. The path of state legislation or regulation providing protections from toxic chemicals is already time-consuming and complex, and the Regulatory Cooperation chapter will make it more so.

tion" with US federal or EU standards.

The current complexity of the regulatory process under California's Prop 65 for listing additional chemicals known to cause cancer helps illustrate this likely outcome. Even though listing and delisting activities are expressly excluded from the requirements of the Administrative Procedure Act, "each procedure already involves, at a minimum, public notice that chemicals are under consideration, solicitation of comments, deliberation on comments received, and notice of the final decision." There are eight separate tracks for listing a chemical, and each involves multiple steps such as:

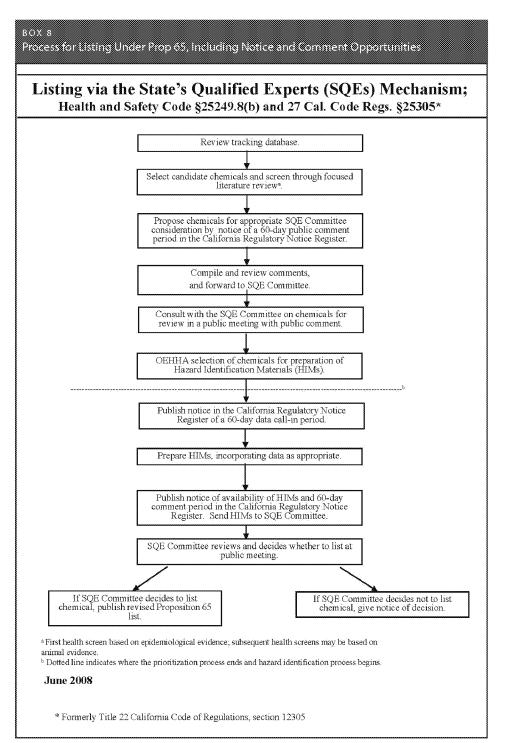
- review tracking database;
- select candidate chemicals and screen through focused literature review;
- propose chemicals for expert review by notice of a 60-day public comment period;
- compile and review comments, and forward to expert committee;
- consult with the expert committee on chemicals for review in a public meeting with public comment;
- select chemicals for preparation of hazard identification materials;
- prepare hazard identification materials, incorporating data as appropriate;
- publish notice in the Register of a 60-day data call-in period;
- publish notice of availability of hazard identification materials and 60-day comment period in the Register;
- send hazard identification materials to

expert committee;

- expert committee reviews and decides whether to list at public meeting;
- if Committee decides to list chemical, publish revised Proposition 65 list; or
- if Committee decides not to list chemical, give notice of decision.

In light of the length, complexity and openness of existing regulatory processes, the likelihood that the additional review, analysis and consultation requirements imposed by TTIP's proposed regulatory cooperation procedures

will needlessly complicate and delay US state health standards such as listing chemicals of concern is self-evident. Further, if chemical regulations such as Prop 65 are subject to trade impact assessments to determine if less trade restrictive alternatives are available, the consequences will be more than procedural; TTIP will be inserting trade and investment considerations that have no place in a public health determination based on science.



# VII. Conclusion

he TTIP regulatory cooperation and coherence proposals threaten the authority and independence of US state governors, legislators, and executive agencies, and could fundamentally alter how public policy is developed, enacted, and implemented in the United States. The EU's proposed Chapter on Regulatory Cooperation in TTIP would significantly impact US state-level chemical policy and disrupt an already complex regulatory and legislative decision process. It would severely limit the authority of states to govern in the public interest, and greatly reduce protections for human health and the environment.

The EU proposal would create an overarching regulatory oversight body to minimize regulatory divergence between the EU and US, potentially erasing protective regulatory differences between the states and subverting longstanding law and policy recognizing federal minimum standards as a floor, not a regulatory ceiling. US federal government oversight of the states' regulatory decision-making would increase, and the concerns of foreign governments would be inserted into domestic policy decisions.

New procedural and substantive requirements would potentially apply to almost all state-level legislation and regulation, and states could be subject to increased legal liability for exercising their Constitutional authority to protect people and the environment. Ironically, the Regulatory Cooperation chapter, designed to promote regulatory compatibility between the US and EU, could instead deter future US state-level chemical policy that builds on the pioneering regulatory model of the EU's REACH (Registration, Evaluation, Authori-



sation and Restriction of Chemicals) program
– an example of "upward harmonization."

Little is known about the US approach to regulatory cooperation in TTIP, including the extent to which US state governance would be affected, because the US refuses to release any textual proposals. Public statements by USTR in support of regulatory coherence and cooperation, including the coordination of regulation through a single federal agency and requiring regulatory impact assessments and cost-benefit analyses, indicate support for concepts included in the EU's Regulatory Cooperation chapter. Powerful industry stakeholders serving as USTR advisors have issued their own regulatory cooperation proposals that explicitly seek to prevent US states and EU Member States from regulating chemicals and pesticides. In the absence of US statements disavowing either the EU or industry proposals, and with the USTR unwilling to release any alternative text, it appears there is little to impede the adoption of Regulatory Cooperation in TTIP.

The ultimate outcome will be to dramatically impair the effectiveness of health and environmental protections across the US and erode the authority of the US states to regulate in the public interest. Not only is this result contrary to the historic role of states as the front-line protectors of public health and safety, it will halt the innovation and responsiveness of state policy-makers to emerging technologies and health threats, leaving millions of Americans at risk.

# Endnotes

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- 7. TSCA Preemption of State Laws and Regulations Briefing Paper, American Bar Association, Section of Environment, Energy, and Resources, 3 (March 1, 2014) available at http://www.americanbar.org/content/dam/aba/administrative/environment\_energy\_resources/whitepapers/tsca/TSCA\_paper

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  1d. at 4. The ABA paper suggests that state-level product warning labels could be preempted under the US Constitution's Commerce Clause if the EPA has required a warning label. Labeling in general is not preempted, however, see e.g., Nat'l Elect. Mfrs. Ass'n v. Sorrell, 272 F. 3d 104 (2d Cir. 2000) (upholding a Vermont statute requiring manufacturers of certain products containing mercury, such as fluorescent light bulbs, to label the products and packaging). Id. at 104.
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    The President's Cancer Panel Report,
    available at http://saferchemicals.org/sc/wpcontent/uploads/sites/3/2013/08/pres-cancerpanel-fs.pdf; see also
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- 12. Because negotiations in the House and Senate are ongoing, this paper does not provide a detailed analysis of the preemption provisions under pending bills for TSCA reform. For a recent analysis of state preemption under TSCA compared to legislation pending in Congress, H.R.2576 (Shimkus) introduced May 26, 2015, and S.697 (Udall-Vitter) as amended April 28, 2015, see Environmental Health Strategy Center, Federal Preemption of the States Under TSCA Reform, 2 (2015) available at <a href="http://www.saferstates.com/assets/FS-Federal-Preemption-of-the-States-Under-TSCA-Reform-Legislation-June.pdf">http://www.saferstates.com/assets/FS-Federal-Preemption-of-the-States-Under-TSCA-Reform-Legislation-June.pdf</a>
- WILLIAM FUNK ET AL., CENTER FOR Progressive Reform, The Truth About Torts: Regulatory Preemption AT THE CSPC, White Paper #807, 1-24, (November 2008) available at http:// www.progressivereform.org/articles/ Truth About Torts CPSC 807.pdf ("[t] he 1981 amendments also require CPSC to halt the development of any new mandatory safety standard if manufacturers have crafted a new voluntary standard to fill a void or address inadequacies in the existing voluntary regime. In design and in practice, the 1981 amendments give manufacturers a right of first refusal to address product safety issues with a design standard). Id. at 9.
- 15 U.S.C. § 2075(a) (2015). States may not establish their own standards where the CPSC

- has adopted a "safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard."
- See CPSIA §§ 218, 231 (2015) (In 2008, following several well-publicized national recalls of toys and children's products, many of which contained lead, Congress passed the Consumer Product Safety Improvement Act (CPSIA) addressing the safety of imported and exported consumer products, including provisions addressing, among other things, lead, phthalates, toy safety, and durable infant or toddler products. While establishing a few specific safety standards in statute, the CPSIA did not change the underlying preemption provisions of the CPSA except to limit preemption by clarifying and preserving the role of state attorneys general in enforcing consumer protections, by prohibiting the Commission from expanding by means of regulation any preemption of state regulation and legal remedies beyond that specified in statute, and by grandfathering certain existing state regulations even where a new standard is adopted). See also John B. O'Loughlin Jr, Consumer Product Safety Improvement: Not the Last Word on Preemption, Product & Safety Liability Reporter, BNA (October 20, 2008); Brandon J. Murrill, Cong. Research SERV. R43297, THE CONSUMER PRODUCTS SAFETY COMMISSION AND INTERNATIONAL Trade: Legal Issues, (2013).
- Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code §§ 25180.7, 25192, 25249.5-25249.13 (West. 1989).
- Lorraine Chow, California Becomes First State to Label Monsanto's Roundup as a Carcinogen, Ecowarch (Sept. 8, 2015), http://ecowarch. com/2015/09/08/california-becomes-firststate-to-label-monsantos-roundup-as-acarcinogen/
- CEG TSCA Report at 23, n. 47 (citing Safer States, Bill Tracker and U.S. State Chemicals Policy Database, Interstate Chemicals Clearinghouse, supra n. 5)
- Interstate Chemicals Clearinghouse, supra n. 5.
- 20. Id. See also Safer States, Bill Tracker, supra n. 5 (explaining that all of these measures focus particularly on substances that are carcinogens, reproductive or developmental toxicants, and endocrine disruptors, and provide for regulation especially where there is likely exposure to children or fetuses and other sensitive or vulnerable populations.) See, e.g., Maine's 2008 "Kid-Safe Toy Act"

and related legislation, 38 MRS, Chapter 16-D, and Maine Department of Environmental Protection, Safer Chemicals in Children's Products, available at http://www.maine.gov/ dep/safechem/ (last visited Sept. 11, 2015). The Minnesota law has similar components; see Minnesota Department of Health, Toxic Free Kids Act: Priority Chemicals, (Nov. 2012) available at http://www.health.state.mn.us/ divs/eh/hazardous/topics/toxfreekids/priority.

Washington State also bans children's products containing lead, cadmium and phthalates, and created a list of chemicals of high concern and requires their disclosure in children's products in 2008, HB 2647 (2008), see Washington Department of Ecology, Children's Safe Products Act,: http://www.ecy. wa.gov/programs/swfa/cspa/ (last visited Sept.

Vermont's Act 188 (2014) and the Vermont Department of Health, Chemical Disclosure Program for Children's Products, http:// healthvermont.gov/enviro/chemical/cdp.aspx (last visited Sept. 11, 2015).

- Daryl Ditz, CIEL Chemicals Program, The Long REACH of Chemical Information, CIEL Blog Post, http://www.ciel.org/77/. In 2010, 4,300 such substances have been "registered," including 3,400 already on the market. The agency estimates that these account for about 90 percent of chemical production in Europe. Similar reporting requirements will apply in June 2013 for chemicals made or imported above 100 tons per year, and to smaller volume chemicals by June 2018. The information contained in these registration "dossiers" includes essential identifiers, such as the chemical's name and formula, and data on inherent properties, such as toxicity and persistence in the environment. Companies are obliged to provide guidance on safe uses, and share this with downstream users.
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- 23. California Department of Pesticide Regulation, A Guide to Pesticide Regulation in California "California's Second Century of Pesticide Regulation", Chapter 1, 1 (2011), available at http://www.cdpr.ca.gov/docs/ pressrls/dprguide.htm
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- A Guide to Pesticide Regulation in California at 19-21, supra n. 23.
- Id. at 22; Birth Control Prevention Act is Chapter 6691, SB 950 (1984).
- Email communication from Charlie L. Clark, Environmental Administrator, Pesticide Registration Review Section, Florida Department of Agriculture and Consumer Services to Sharon Treat (June 24, 2015).
- State regulators "perform an extensive review

- of pesticide products which contain new active ingredients and/or are considered to represent major changes in labeling." Email from Jeanine Broughel, Chief, Pesticide Product Registration Section, New York State Department of Environmental Conservation, to Sharon Treat (June 25, 2015). For information regarding New York's pesticide product registration program, see New York State DEC, Pesticide Product Registration, http://www.dec.ny.gov/chemical/8528.html (last visited Sept. 18, 2015).
- FLA. STAT. § 487.041 (2015); See also email communication from Charlie L. Clark to Sharon Treat (June 24, 2015).
- 31. Id. at 22; Birth Control Prevention Act of 1984, Cal. Food & Agric. Code §§ 13121-13135. (West 2015)
- A Guide to Pesticide Regulation in California at 22, supra n. 23. The report does not specify how many of these were withdrawn by manufacturers and how many were suspended by the state.
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- Telephone interview with Royan Teter, Chief, Pesticides Section, Toxics and Pesticides Branch, Region 7, U.S. Environmental Protection Agency (June 19, 2015).
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- For details of state regulatory authority and links to state contacts and information, see EPA, Pesticides: Regulating Pesticides, http://www.epa.gov/pesticides/regulating/ (last visited Sept. 11, 2015), and National Pesticide Information Center, State Pesticide Regulation, http://npic.orst.edu/reg/regstate. html (last visited Sept. 11, 2015). In addition to the EPA, the federal Food and Drug Administration (FDA) has some overlapping jurisdiction, as does the US Department of Agriculture.
- Telephone interview with Royan Teter, supra n. 34.
- Email communication from Tim Creger , Pesticide/Fertilizer Program Manager, Nebraska Department of Agriculture, to Sharon Treat (June 18, 2015)
- EPA, Pesticides: Regulating Pesticides, Food Quality Protection Act, FFDCA Amendments, EPA, http://www.epa.gov/pesticides/ regulating/laws/fqpa/fqpaffdc.htm (last visited Sept. 18, 2015).
- 41. Id.
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- 43. A Guide to Pesticide Regulation in California at 77, supra n. 23.
- National Conference of State LEGISLATURES (NCSL), http://www.ncsl.org/ research/environment-and-natural-resources/ pollinator-health.aspx (last visited Sept. 11,

- 2015). NCSL maintains a public database of legislation relating to pollinator health. This trend continued in 2015 with legislation introduced in the following states to label, prohibit or restrict the use of neonicotinoids: VERMONT: H. 236, 2015-2015 General Assembly Sess. (Vt.) available at http://legislature.vermont.gov/bill/ status/2016/H.236; MASSACHUSETTS: H. 65, 189th Gen. Court (Ma. 2015) available at https:// malegislature.gov/Bills/189/House/H655; MINNESOTA: H.F. 2029, 89th (MN 2015) available at http://wdoc.house.leg.state. mn.us/leg/LS89/HF2029.0.pdf; MAINE:H.P. 766, 127th Sess.,, First Reg. Sess. (Me. 2015) available at http://legislature.maine.gov/legis/ bills/display ps.asp?LD=1105&snum=127; ALASKA: H.B. 20, 29th Sess. (AL 2015) available at http://www.akleg.gov/basis/Bill/ Detail/29?Root=HB%20%2020; NEW JERSEY: No. 1373, 216th legis. (NJ 2014) available at http://www.njleg.state. nj.us/2014/Bills/A1500/1373 I1.HTM
- See NCSL database, supra n. 44 (listing 2014 and 2015 state fracking legislation as of June 2015); See also Jacquelyn Pless, Fracking Update: What States are Doing to Ensure Safe Natural Gas Extraction, NSCL (June 2011) http://www.ncsl.org/research/energy/frackingupdate-what-states-are-doing.aspx Id.
- 46.
- For links to local ordinances, see Food and Water Watch, Local Actions Against Fracking http://www.foodandwaterwatch.org/water/ fracking/anti-fracking-map/local-actiondocuments/ (last visited Sept. 18, 2015). Measures adopted in states including Texas, Oklahoma, Arkansas, and North Dakota range from well permitting requirements, disclosure of HVHF ingredients, and water protection measures (Texas, Arkansas) to a legislative declaration that hydraulic fracturing is an acceptable recovery process (North Dakota); see also Erica Levine Powers, Home Rule Meets State Regulation: Reflections on High-Volume Hydraulic Fracturing for Natural Gas ABA, http:// www.americanbar.org/publications/state\_ local\_law\_news/2011\_12/winter\_2012/ home\_rule\_state\_regulation.html (last visited Sept. 18, 2015).
- This analysis is of the text tabled for discussion by the EU in the April 20-24, 2015 negotiating round and made public on May 4, 2015. It is posted on the website of the European Commission here: European Commission, Trade: Now online-EU negotiating texts in TTIP, (Feb. 10, 2015) http://trade.ec.europa.eu/doclib/press/index. cfm?id=1230
- EU, TTIP- Initial Provisions for Chapter []-Regulatory Cooperation, Article 1 a-d, avialable at http://trade.ec.europa.eu/ doclib/docs/2015/april/tradoc\_153403.pdf (hereinafter "EU, TTIP")
- See Id. at n.4. (clarifying Article 3.1 applying the provisions of Section II of the chapter on Good Regulatory practices to central governments: " [f]urther reflection will be required regarding regulatory acts at non-central level") Id; See also Id. at n. 6 (concerning how regulations with a "significant impact" on trade or investment will be identified: "[f]urther discussion will be needed on how to identify these acts at the non-central level); Id. Article 8 (bracketed text: "[p]laceholder for further details on the Focal points at the non-central

- level" concerning the Bilateral Cooperation Mechanism); *Id.* Article 11.5 (bracketed text relating to regulatory acts at the non-central level in [specific or sectoral provisions *to be identified*]).
- 51. The text defines "regulators and competent authorities at non-central level" for the US as "the central authorities of a US State" seemingly excluding the District of Columbia and US territories and countries in commonwealth status, *Id.* Article 2.d.ii.
- 52. Id. at n 4.
- 53. Id. Article 2.c-d.
- 54. Id. Article 8.3, Article 9
- 55. Id. Article 11.2. see also Id. at n.8 (identifying "planned acts" at the central level as including "draft regulatory acts proposed by the US Administration to Congress" and "bills introduced by Congressmen.")
- 56. Id. Article 11.2
- Id. at n. 17.
- European Commission, Detailed Explanation on the EU Proposal for a Chapter on Regulatory Cooperation 7 (6 May 2015), available at http://trade.ec.europa.eu/doclib/docs/2015/ may/tradoc\_153431.1.1%20Detail%20 explanation%20of%20the%20EU%20 proposal%20for%20a%20Chapter%20 of%20reg%20coop.pdf
- 59. See EU, TTIP, supra n. 49, Article 11.1. "The regulators and competent authorities at non-central level concerned will determine their interest in entering into a regulatory exchange," Id. at Article 11.3. On the other hand, other language in Article 11 seems to require the federal government to make them happen, employing "will" and "shall" language throughout, see also Id. Article 11.2, 11.3, and n. 17.
- 60. Id. Article 11.3. State officials are also supposed to keep the federal Focal Points "duly informed" about direct contacts and regulatory exchanges they may undertake on their own initiative with EU regulators. See Id. at n. 14.
- 61. Id. Article 11.5.
- The SPS chapter is posted online, see EU, Textual Proposal: Sanitary and Phytosanitary Measures (SPS), (January 7, 2015) http:// trade.ec.europa.eu/doclib/docs/2015/ january/tradoc 153026.pdf; see also Steve Suppan, Analysis of the European Commission Proposal for the Sanitary and Phytosanitary Measures Chapter of the Transatlantic Trade and Investment Partnership Agreement, Institute for Agriculture and Trade Policy 2 (February 4, 2015), for a discussion of regulatory cooperation measures. The TBT chapter is posted online as well. See, EU, Textual Proposal: Technical Barriers to Trade (TBT) (January 7, 2015) http://trade. ec.europa.eu/doclib/docs/2015/january/ tradoc 153025.pdf.
- 63. Supra n. 18.
- 64. EU, Fact Sheet on Regulatory Cooperation in TTIP, 6, available at http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc\_153002.1%20RegCo.pdf (last visited Sept. 11, 2015)
- 65. The RCB has sweeping authority to request early advance notice of legislation and regulations, and to require pre-adoption trade and investment impact assessments. Retrospective reviews of existing laws and regulations are also authorized. Industry stakeholders, among others, would be invited to "provide input" as regulatory acts are undergoing impact assessments; these interventions would be in addition to and

- outside of the usual notice-and-comment rulemaking procedures applicable to federal and state agencies, and regulators "shall take into account" this input. Multiple rounds of information exchanges, including "relevant evidence and data" and "methodology and economic assumptions" would be required. Sectoral working groups are authorized to initiate "specific cooperation initiatives related to regulatory acts at the non-central level". See E.U. TTIP, supra n. 49, Article 14.1 and n.13 and 20 for applicability to non-central governments.
- 66. Id. at n. 13
- 67. Id. at n. 14
- 68. Id. Article 2.c.
- 69. Id. Article 3.1.a and 3.1.b. With most of TTIP yet to be negotiated and few textual proposals publicly available, it is unknown what may be excluded from the final agreement. As an example, in prior EU trade agreements, France has excluded audiovisual services.
- EU, TTIP and Regulation: An Overview, 17 (February 2015) available at http://trade. ec.europa.eu/doclib/docs/2015/february/ tradoc\_153121.pdf
- 71. Id
- These examples are consistent with both the recently negotiated EU-Canada Comprehensive Economic and Trade Agreement (CETA) and European environmental services offers in the World Trade Organization GATS (General Agreement on Trade in Services) negotiations. The environmental services offer in GATS included: water for human use & wastewater management, solid/hazardous waste management, protection of ambient air and climate, remediation and cleanup of soil & water, noise & vibration abatement. protection of biodiversity and landscape, and various other services with an environmental component including business services, R&D, consulting, contracting & engineering, construction, distribution, and transport. See WTO, Communication from the European Communities and Their Member States, GATS 2000: Environmental Services (December 22, 2000), available at, https://www.wto.org/ english/tratop e/serv e/s propnewnegs e. htm The CETA definition of covered services is very broad with few exceptions, see WTO, Consolidated CETA Text 188-189 (September 26, 2014), available at, http://trade. ec.europa.eu/doclib/docs/2014/september/ tradoc\_152806.pdf
- Behind the Veil: The Truth About Trade in Environmental Goods', SIERRA CLUB (April 22, 2014), http://www.sierraclub.org/ compass/2014/04/behind-veil-truth-abouttrade-environmental-goods
- 74. EU, TTIP, supra n. 49, Article 3.2
- See EU position papers on a potential cosmetics annex: European Commission, The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues: Cosmetics, 1-4 (2015) available at http:// trade.ec.europa.eu/doclib/docs/2014/may/ tradoc 152470.pdf; European Commission, The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues: Chemicals, 1-4 (2014) available at http:// trade.ec.europa.eu/doclib/docs/2014/ may/tradoc 152468.pdf; European Commission, The Transatlantic Trade and Investment Partnership (TTIP): Energy and Raw Materials, 1-4 available at http:// trade.ec.europa.eu/doclib/docs/2013/july/

- tradoc 151624.pdf (last visited Sept. 11, 2015)
- 76. EU, Fact Sheet on Regulatory Cooperation in TTIP supra n. 64 at 6.
- 77. EU, TTIP, supra n. 49, Article 2.c.
- 78. See also Id. at n. 2 (asserting that the chapter's provisions "cannot be interpreted or applied as to oblige either Party to change its fundamental principles governing regulation in its jurisdiction, for example in the areas of risk assessment and risk management.")
- 79. Id. General notes, paragraph 4.
- 80. Id.
- See, e.g., USTR, Non-Tarrif Barriers and Regulatory Issues, https://ustr.gov/ trade-agreements/free-trade-agreements/ transatlantic-trade-and-investmentpartnership-t-tip/t-tip-2 (last visited Sept. 11, 2015). The USTR issue statement "Non-tariff Barriers and Regulatory Issues" mentions "greater transparency, participation and accountability in the development of regulations;" "evidence-based analysis and decision-making;" "a whole-of-government approach to regulatory management;" and "examining ways to increase regulatory compatibility in specific sectors through a range of regulatory cooperation tools as well as other steps aimed at reducing or eliminating unnecessary regulatory differences.'
- 82. This undated document was leaked in 2011, and may not reflect language to which the parties will ultimately agree.
- 83. For analysis, see Jane Kelsey, Preliminary Analysis of the Draft TPP Chapter on Domestic Coherence, (23 October 2011) http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacific RegCoherenceMemo.pdf and Bill Waren The TPP trade agreement regulatory coherence chapter is an environmental hazard (June 1, 2012), Friends of the Earth, http://www.foe.org/news/archives/2012-06-the-tpp-trade-agreement-investment-chapter-is-an-env#sthash.EdODeplc.dpufhttp://www.foe.org/news/archives/2012-06-the-tpp-trade-agreement-investment-chapter-is-an-env#sthash.EdODeplc.dpufhttp://www.foe.org/news/archives/2012-06-the-tpp-trade-agreement-investment-chapter-is-an-env
- 84. See Michael Froman, US Trade
  Representative, Remarks from the
  Transatlantic Trade and Investment
  Partnership First Round Opening Plenary(
  July 8, 2013), available at https://ustr.gov/
  about-us/policy-offices/press-office/speeches/
  transcripts/2013/july/amb-froman-ttipopening-plenary
- 85. HLWG, Final Report, High Level Working Group on Jobs & Growth, 3-4 (February 11, 2013), available at http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc\_150519.pdf. The report recommends early consultations on significant regulations, increased use of impact assessments, promoting harmonization of future regulations, periodic review of existing regulatory measures to "reduce burdens" through equivalence, mutual recognition, or other means, and an ongoing entity to guide future regulatory cooperation.
- 86. US Chamber of Commerce, Regulatory
  Coherence & Cooperation in the Transatlantic
  Trade and Investment Partnership (February
  27, 2015), available at https://www.
  uschamber.com/report/regulatory-coherencecooperation-transatlantic-trade-andinvestment-partnership-ttip. The Chamber
  states that TTIP "must remove obstacles to
  ... cooperation" and lists five elements to
  achieve this: (1) TBT commitments; (2) SPS

- measures, with a focus on the precautionary principle; (3) Sector-specific regulatory arrangements; (4) Regulatory Coherence, and (5) Regulatory Cooperation. The Chamber's vision of regulatory coherence includes impact statements, including non-regulatory or voluntary alternatives; cost-benefit analysis for each available alternative including no regulation; the necessity test -- identify and select the "least burdensome approach necessary to achieve legitimate regulatory objective"; using a risk based approach "wherever possible"; and central domestic coordination.
- Umwelt Bundesamt, Environmental PROTECTION UNDER TTIP 2 (Federal Environment Agency, 2015) available at: https://www.umweltbundesamt.de/sites/ default/files/medien/376/publikationen/ environmental protection under ttip 0.pdf
- Id., Preliminary Analysis of the Draft TPP Chapter on Domestic Coherence, at 1.
- 89,
- 90. NCLS (March 2013), http://www.ncsl.org/ research/about-state-legislatures/number-oflegislators-and-length-of-terms.aspx
- NCSL, Full- and Part-Time Legislatures (June 2014), http://www.ncsl.org/research/ about-state-legislatures/full-and-part-timelegislatures.aspx
- The USTR's consultation with state governments is described on an archived USTR website: USTR, Archive, https:// ustr.gov/archive/Benefits of Trade/States/ How USTR consults with State Local Governments.html (last visited Sept. 18, 2015). USTR also maintains an advisory committee of non-federal government officials, the Intergovernmental Advisory Committee (IGPAC), which currently includes one state legislator. IGPAC has been criticized as ineffective and underresourced by its own members, see Kay Wilke, IGPAC, RECOMMENDATIONS FOR IMPROVING FEDERAL-STATE TRADE POLICY COORDINATION (August 5, 2004), available at https://www.citizen.org/documents/ IGPAC\_Recommendations\_Federal\_State\_ Coordination.pdf
- Office of Management and Budget, OIRA, https://www.whitehouse.gov/omb/oira (last visited Sept. 11, 2015)
- See, e.g., Steinzor, et al, Center for PROGRESSIVE REFORM, BEHIND CLOSED DOORS AT THE WHITE HOUSE: HOW Politics Trumps Protection of Public HEALTH, WORKER SAFETY, AND THE Environment, (2011); Lisa Heinzerling, Inside EPA: A Former Insider's Reflections on the Relationship Between the Obama EPA and the Obama White House, 31 PACE ENVIL L. Rev. 325 (2014) available at http:// digitalcommons.pace.edu/cgi/viewcontent. cgi?article=1741&context=pelr
- 95.
- CURTIS W. COPELAND, OFFICE OF Information and Regulatory Affairs, LENGTH OF RULE REVIEWS BY THE OFFICE OF INFORMATION AND REGULATORY Affairs, 28 (October 7, 2013), available at https://www.acus.gov/sites/default/files/ documents/Copeland%20Report%20 CIRCULATED%20to%20Committees%20 on%2010-21-13.pdf
- Jim Morris et al., Slow Motion Tragedy FOR AMERICAN WORKERS (Center for Public Integrity 2015), available at http://www. publicintegrity.org/2015/06/29/17518/ slow-motion-tragedy-american-

- workers?utm source=email&utm campaign=watchdog&utm\_medium=publiciemail
- LISA HEINZERLING AND FRANK ACKERMAN, GEORGETOWN ENVIL. LAW AND POLICY INST., Georgetown Univ. Law. Center, Pricing THE PRICELESS: COST-BENEFIT ANALYSIS of Environmental Protection (2002), available at http://www.ase.tufts.edu/gdae/ publications/C-B%20pamphlet%20final.pdf
- See Kelsey, supra n. 83, at 4 ("[t]he RIA [Regulatory Impact Analysis] could provide evidential material that has been prepared by the government itself, either as evidence to support a complaint or as an evidential basis for the dispute").
- 100. Public Citizen, Case Studies: Investor-State Attacks on Public Policies, http://www.citizen. org/documents/egregious-investor-stateattacks-case-studies.pdf (last visited Sept. 18,
- 101. These threats are acted upon, too. See e.g., Nat'l Elect. Mfrs. Ass'n v. Sorrell, 272 F. 3d 104 (2d Cir. 2000) (upholding a Vermont statute requiring manufacturers of certain products containing mercury, such as fluorescent light bulbs, to label the products and packaging state regulation of mercury); see also Grocery Mfrs Ass'n v. Sorrell, (challenging Vermont's genetic engineering food labeling requirements). The case is pending; litigation documents are posted here: Vermont Office of the Attorney General William H. Sorrell, GE Food Litigation, http://ago.vermont.gov/hot-topics/gefood-litigation.php (last visited Sept. 18, 2015). The American Chemistry Council, Biotechnology Industry Organization, U.S. Chamber of Commerce and the Agricultural and Commodity Trade Associations, among others, are supporting plaintiffs' challenge as amicus curiae.
- 102. Public Citizen, Case Studies, supra n. 100.
- 103. See Letter from National Associations of Attorneys General to Michael Froman, Ambassador to the Office of the United States Trade Representative, (February 5, 2014,) available at http://www.naag.org/ assets/files/pdf/signons/2014-02-05%20 TPP%20Final%20Letter1.pdf. ("A recent example of such a challenge is a NAFTA investor arbitration brought by Grand River Enterprises Six Nations Ltd., a Canadian cigarette manufacturer that challenged certain MSA- related laws in 45 states - laws that have been upheld in every challenge to them in a United States court, including several by Grand River itself. The NAFTA challenge was rejected by an arbitration panel, but only after extensive litigation that consumed significant state and federal time and resources to defend").
- 104. Corporate Europe Observatory (CEO), Toxic Affair (2015).
- 105. U.S. Government, Comments of the US Government, European Commission's Public Consultation on Defining Criteria for Identifying Endocrine Disruptors (EDs) in the Context of the Implementation of the Plant Protection Product Regulation and Biocidal Products Regulation (Jan. 16, 2015), available at: http://www.usda-eu.org/wp-content/ uploads/2015/01/United-States-Submission-Endocrine-Disrupters-2015-01-20.pdf
- 106. USCIB, The United States Council for International Business Submission to USTR on The Transatlantic Trade and Investment Partnership 11 (May 10, 2013) available at http://www.uscib.org/docs/2013\_05\_14\_

- ttip\_submission.pdf
- 107. Steve Suppan, Analysis of the European Commission proposal for the Sanitary and Phytosanitary Measures Chapter of the TTIP Institute for Agriculture and Trade Policy, supra n. 62 at 4.
- 109. California, Connecticut, Delaware, Illinois, Maine, Minnesota, Nevada, New York, Washington, Wisconsin, see Safer States database of state legislation, supra n. 5.
- 110. EU, TTIP, supra n. 49, Article 10.2.b.
- 111. Croplife America, European Crop Protection Association and CropLife America Proposal on US-EU Regulatory Cooperation (March 7, 2014), http://www.croplifeamerica.org/ sites/default/files/ECPA-CLA%20TTIP%20 Position%20-%20Paper%2010-03-14.pdf
- 112. CIEL, Lowest Common Denominator: How the Proposed US-EU Trade Deal Threatens to Lower Standards of Protection from Toxic Pesticides, 13, and Table 2 (January 2015), available at http://www.ciel.org/reports/lowest-commondenominator-how-the-proposed-us-eutrade-deal-threatens-to-lower-standards-ofprotection-from-toxic-pesticides/
- 113. Suppan, Analysis of the European Commission SPS Proposal, supra n. 62 at p. 4
- 114. A Guide to Pesticide Regulation in California, supra n. 23 at 77.
- 115. California Office of Environmental Hazard Assessment, Mechanisms for Listing and delisting Chemicals under Proposition 65, (May 15, 2007) http://oehha.ca.gov/prop65/ policy procedure/listde051007.html